

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:)	
Cesare Gianturco)	Before the Examiner
Serial No. 244,669)	Dalton Truluck
Filed September 14, 1988)	Group Art Unit 336
ENDOVASCULAR STENT AND)	
DELIVERY SYSTEM)	

DECLARATION OF DR. CESARE GIANTURCO

I, Cesare Gianturco, M.D., hereby state as follows:

1. I am a physician currently engaged in experimental radiology and the investigation of vascular diseases. Prior to November 7, 1985, I conceived and reduced to practice the invention hereinafter described.

2. Prior to November 7, 1985, I wrapped a wire composed of a malleable metallic material around an angioplasty balloon in a U-inverted U fashion, or in a series of alternating clockwise and counterclockwise helical sections, to form an implantable stent. I conducted bench tests of this apparatus in which the balloon was supported on a fixture so as to allow the balloon be inflated. The balloon was inflated to expand the wire stent whereby the cusps of the alternating helical sections moved relatively apart.

3. Prior to November 7, 1985, I directed and observed an in vivo test of the balloon-expanded stent described above. I observed Dr. Kenneth Wright insert an angioplasty balloon with the wire stent engaged thereabout into the external iliac artery of a live dog. The balloon was inflated to expand the stent into contact with the artery wall, which was verified by radiograph of the implantation region. After it was determined by radiograph observation that the stent had been properly

positioned in the artery, the balloon was deflated. After verifying that the stent had been securely implanted in the artery wall, the balloon catheter was removed.

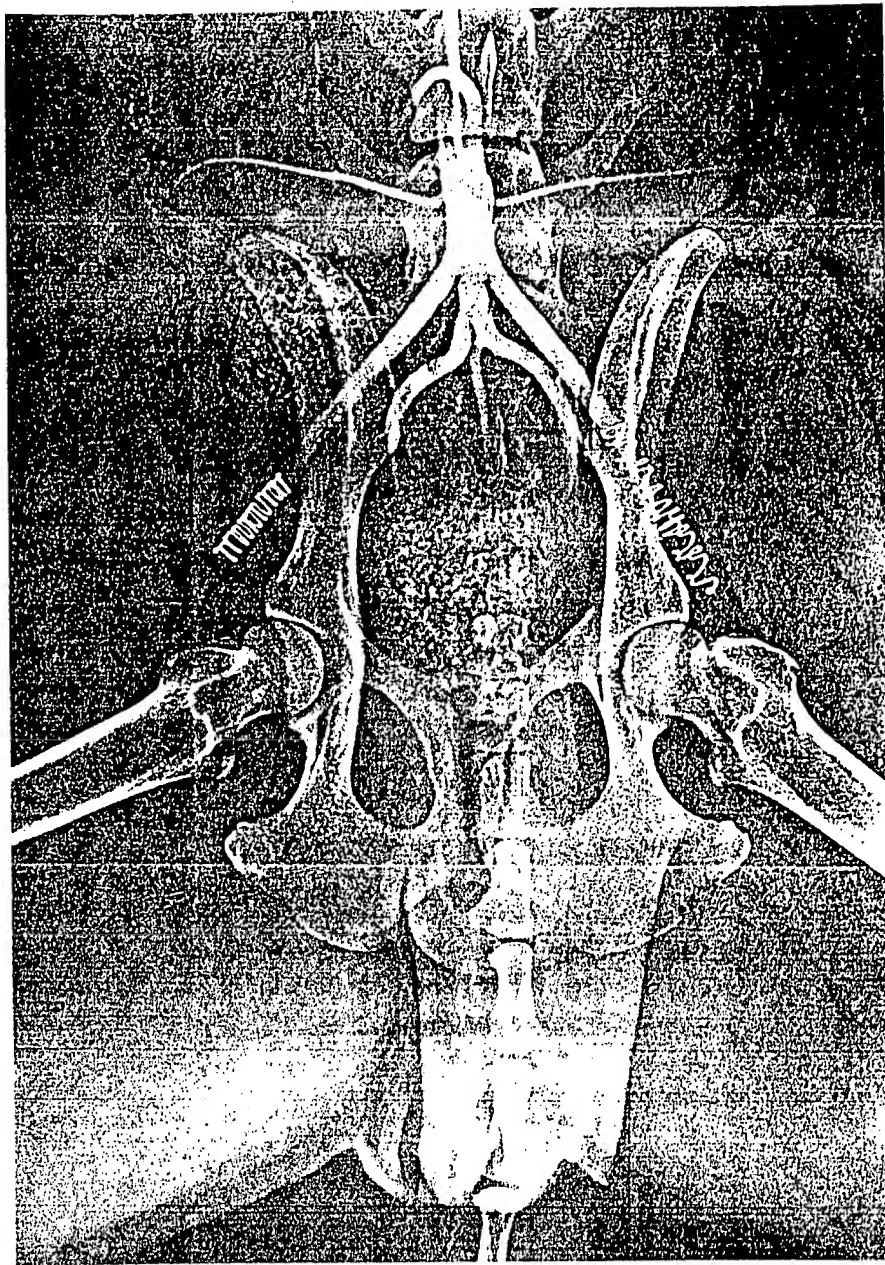
4. I also observed Dr. Wright insert a second balloon catheter with a stent engaged thereabout into the other external iliac artery of the same dog. After the balloon catheter and stent had been directed through the artery to the implantation site, radiography revealed that the stent had displaced slightly on the balloon catheter. The balloon was inflated to expand a portion of the stent into contact with and implanted in the artery wall. The balloon was then deflated and advanced into the unexpanded portion of the stent, wherein the balloon was re-inflated to expand the remaining portion of the stent.

5. Attached to this Declaration is a photocopy of a radiograph image taken of the implantable balloon-expanded stent during the above described in vivo tests. Also attached is a photocopy of a study report describing the in vivo tests. I attest that these photocopies are true and complete copies of the actual radiograph image and study report, and that the radiograph image and study report are true and authentic and were created during the above described in vivo tests.

6. All statements made in this Declaration of my own knowledge are true, and all statements made on information and belief are believed to be true. This Declaration has been made and signed with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. §1001) and may jeopardize the validity of this application or any patent issuing thereon.

Date: Dec. 18th 1988

Cesare Gianturco M.D.
Cesare Gianturco, M.D.



Xerogram Taken of dog 1A 162
on 1/6/82 - Cesare Giunturo MD

Stints

STUDY #

Dog # 1A-162

Date Issued 12-7-81

Study Date 12-10-81

Sac Date 1-6-82

Wt. 21 kg

Sex

♀

Condition Chronic

Anesthesia

Investigator C. Hunter

Radiographs taken

Kept

12-10-81

Wire stints were placed in the iliacs. Xerograms difficult in putting stints in place. Would come off the balloon before inflation.

1-6-82

Lower abd aortogram (Xero) for stints. Both stints causing restrictions in vessel.

Vena Cavaogram + Portogram were done to determine distance between the 2 vessels.

Dog 000

Cesare Hunter M.D.